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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,040	07/24/2003	Michael Lebner	0156-2008US01	1249

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EXAMINER

PETRIK, KARI KRISTEN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/626,040	Applicant(s) LEBNER, MICHAEL	
	Examiner Kari Petrik	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-20 and 22-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-20 and 22-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
 - 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed on 2/23/2006 has been received and made of record. As requested, claims 1, 3, 20, and 22 have been amended and claims 2, and 21 have been cancelled.
2. Claims 1, 3-20, and 22-38 are pending in the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-20, and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebner (US Patent 6,329,564) in view of Lutri et al (US Patent Application Publication 2004/0106888).
5. As regards claim 1, Lebner discloses a two-component device for closing a laceration or incision, comprising: a first component (5) comprising a first adhesive-backed anchoring member and one or more first connecting members (15) extending from one edge thereof in a first direction, a second component (25) comprising a second adhesive-backed anchoring member and one or more second connecting members (35) extending from one edge thereof in a second direction generally opposite to the first direction, and adhesive means for attaching the one or more first connecting members to the second anchoring member and means for attaching the one or more

second connecting members to the first anchoring member, the attachment of the connecting members to the anchoring members forming attached and bridging portions of the one or more connecting members, the attached portions being attached to an anchoring member, and the bridging portions spanning the over-laceration area between the first and second anchoring members (col. 5, lines 51-52 and col. 5, line 64-col. 6, line 1). Lebner discloses that the connecting members are made from an inelastic polymeric material.

As regards claim 4, note pulling elements (40, 45) and col. 5, lines 58-64.

Regarding claim 6, Lebner discloses that the pulling element and extensions of the connecting members are removable at the perforations (17, 37) following application of the device. The applicant should note that the extension of the connecting members is defined as the portion of the connecting member severed with pulling elements (40, 45).

Regarding claim 11, note col. 1, lines 43-46 and col. 1, line 66-col. 2, line 2, which disclose adhesive means.

Regarding claim 10, Lebner discloses that the device is constructed from a vapor-permeable (*i.e.*, allow for the exchange of air) material (col. 3, lines 5-15).

Regarding claims 12 and 14, in col. 1, lines 48-65, Lebner discloses that both the anchoring members and the connecting members are protected by release liners, and that the first and second anchoring members are protected by first and second release liners (col. 1, lines 48-65).

Regarding claims 18 and 19, note the disclosure of reinforcements at col. 2, lines 60- col. 3, line 4.

Regarding claim 20, mere use of the modified device of discussed above in the rejection of claim 1 above obviates the claimed invention. The applicant should note that manipulating the pulling elements for attachment onto the anchoring member such that the wound or laceration is closed, necessarily involves adjusting the position of anchoring members in both an x and y dimension.

Regarding claims 23, 25, 29-31,33, 37 and 38, note the rejection of claims 4, 6, 10-12,14,18 and 19, respectively.

6. Regarding claims 5, 7-9, 13,15-17, 24, 26-28, 32, and 34-36, Lebner fails to teach that the pulling elements are coded to enable user distinction, that the coding comprises an observable geometric distinction between the shape of the pulling elements and the shape of the anchoring members, that the coding comprises printed indicia enabling user distinction between pulling elements and anchoring members, that the coding on the pulling elements comprises distinguishing colors, or that the anchoring members are provided with one or more alignment indicators.

However, Lebner discloses at col. 4, lines 38-53, that the bandage can include wound closure visual alignment indicators, and further discloses at col. 5, lines 1-21, that the bandage can include indicia (e.g., color, graphic representations, etc.) for the purpose of indicating specific information to the user (e.g., tension).

In light of these disclosures, it would have been *prima facie* obvious to one

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having ordinary skill in that art at the time of invention to provide any portion of the Lebner bandage with indicia of various types (*e.g.*, colors, shapes, printed material, *etc.*) in order to indicate any information.

7. Regarding claims 1, 3, 20 and 22, Lebner does not disclose that the first and second components are made of an elastic polymeric material. Lutri et al. teach a two-component device for closing a laceration or incision comprising first and second components (10a&b) and a connecting member (11), wherein the first and second components can be made of an elastic polymeric material (paragraph 0014). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the wound closure bandage disclosed by Lebner having first and second components made of an elastic material, as taught by Lutri et al., to provide greater comfort to the user's skin.

8. Claims 1, 3-20, and 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebner in view of Beaudry (US Patent 6,982,359). Lebner discloses a two-component device for closing a laceration as described in the rejection above wherein the anchoring members and connectors are made of an inelastic polymeric material. Beaudry teaches a two-component device capable of closing a laceration wherein the first and second components and the connectors are made of different materials, and specifically discloses the first and second components are made of an elastic material (column 2 line, 65 –column 3 line 5). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the

two-component bandage disclosed by Lebner having elastic components, as taught by Beaudry, to impart different physical characteristics to different parts of the device.

Double Patenting

9. Claims 1, 3-20, and 22-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 7 of U.S. Patent No. 6,822,133 B2 ("the '133 patent") in view of U.S. Patent No. 6,329,564 B1 ("Lebner") in further view of Lutri et al (US Patent Application Publication 2004/0106888).

It is clear that substantially all the limitations of claims 1 and 20 of the present application are to be found in claims 1 and 7 of the '133 patent except that the components and connecting members are produced from a first and second polymeric material. Lebner teaches a bandage having connecting members produced from an inelastic polymeric material. Lutri et al further teaches a bandage wherein the first and second components are produced from an elastic polymeric material. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

With respect to claims 4-19 and 23-38, the '133 patent fails to teach these limitations. However, Lebner either explicitly discloses these features or renders obvious these features. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

10. Claims 1, 4-20 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-18 and 20-34 of copending Application No. 10/625937 ("the '937 application") in view of Lutri et al (US Patent Application Publication 2004/0106888).

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that substantially all limitations of claims 1, 4-20 and 23-38 of the instant application are to be found in claims 1, 3-18 and 20-34 of the '937 application. The only limitation not present in claims 1, 3-18 and 20-34 of the '937 application is that the components and connecting members are produced from first and second polymeric materials. Lutri et al teaches a bandage wherein the components and connecting members are produced from separate materials. Applicant's attention is directed to the rejection of these claims above.

This is a provisional obviousness-type double patenting rejection.

11. Claims 1, 4-20 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-19 and 21-36 of copending Application No. 10/626,783 ("the '783 application") in view of Lutri et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that substantially all limitations of claims 1, 4-20 and 23-38 of the instant application are to be found in claims 1, 3-19, and 21-36 of the '783

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application. The only limitation not present in claims 1, 3-19 and 21-36 of the '783 application is that the components and connecting members are produced from first and second polymeric materials. Lutri et al teaches a bandage wherein the components and connecting members are produced from separate materials. Applicant's attention is directed to the rejection of these claims above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1, 4-13, 17-20 and 23-32, 34 and 36-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 16-30 and 32-34 of copending Application No. 10/625,785 ("the '785 application") in view of Lutri et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because substantially all limitations of claims 1, 4-20 and 23-38 of the instant application are to be found in claims 1-12, 16-30 and 32-34 of the '785 application. The only limitation not present in claims 1-12, 16-30 and 32-34 of the '785 application is that the components and connecting members are produced from first and second polymeric materials. Lutri et al teaches a bandage wherein the components and connecting members are produced from separate materials. Applicant's attention is directed to the rejection of these claims above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1, 4-20 and 23-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Application No. 10/625,936 ("the '936 application") in view of Lutri.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that the limitations of claims 1, 4-20 and 23-38 of the instant application are found in claims 1-34 of the '936 application. The only limitation not present in claims 1-34 of the '936 application is that the components and connecting members are produced from first and second polymeric materials. Lutri et al teaches a bandage wherein the components and connecting members are produced from separate materials and wherein the components are made from an elastic material. Applicant's attention is directed to the rejection of these claims above. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of copending Application No. 10/938,163 ("the '163 application") in view of Lutri et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that substantially all of the limitations of claims 1 and 20 of the instant application are found in claims 1 and 16 of the '163 application. The differences merely amount to wording changes and that the components and

connecting members are produced from first and second polymeric materials. Lutri et al teaches a bandage wherein the components and connecting members are produced from separate materials and wherein the components are made from an elastic material. Applicant's attention is directed to the rejection of these claims above.

Another difference is that the abstract of the instant invention recites a two-component device for closing a laceration or incision, while the '163 patent recites a two-component medical device. However, the applicant should note that the preamble is denied the effect of a limitation where the claim is drawn to structure and the portion of the claim following the preamble is self-contained description of the structure not depending for completeness upon the introductory clause.

This is a provisional obviousness-type double patenting rejection.

15. Claims 1 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of U.S. Patent No. 6,831,205 ("the 205 patent") in view of Lutri et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is clear that substantially all of the limitations of claims 1 and 20 of the instant application are found in claims 1 and 16 of the '205 patent. The only limitation not present in claims 1 and 16 of the '205 patent is that the components and connecting members are produced from first and second polymeric materials. Lutri et al teaches a bandage wherein the components and connecting members are produced from separate materials and wherein the components are made from an elastic

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material. Applicant's attention is directed to the rejection of these claims above.

Another difference is that the abstract of the instant invention recites a two-component device for closing a laceration or incision, while the '163 application recites a two-component medical device. However, the applicant should note that the preamble is denied the effect of a limitation where the claim is drawn to structure and the portion of the claim following the preamble is self-contained description of the structure not depending for completeness upon the introductory clause.

16. Claims 4-19 and 23-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 16 of the '205 patent in view of Lutri et al in further view of Lebner.

With respect to claims 4-19 and 23-38, the '205 patent fails to teach the limitations recited therein. However, Lebner either explicitly discloses these features or renders obvious these features. Applicant's attention is directed to the rejection of these claims above. The applicant should note that the same rationale for combining this reference above also apply in this double patenting rejection.

Response to Arguments

17. Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kari Petrik whose telephone number is 571-272-8057. The examiner can normally be reached on M-Th 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KKP

Kari Petrik
Examiner
Art Unit 3743

Kari Petrik
5/8/06

Henry Bennett
Henry Bennett
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